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Evaluating the effectiveness of acupuncture in defined aspects of stroke recovery.

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/01/2010	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SPGS816

Study information

Scientific Title

Study objectives
Acupuncture in addition to conventional treatment will have a greater effect on recovery from stroke than intervention by a placebo/control.
Background: Acute stroke counts for 12% of all death in Britain and an expected incidence of 500 per 250000 head of population, 40% of which will be admitted to hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cerebrovascular disease

Interventions
Both groups will receive rehabilitative care and one of two treatment groups.
1. Acupuncture treatment will consist of dry needling to 3 out of 4 points in the upper limb chosen from; LI4, LI10, SJ5, LI15 with GB20 and 4 out of 5 in the lower limb GB43, BG39, GB34, GB30, ST36. Scalp acupuncture will also be used. The scalp over the motor cortex being stimulated with dry needles to which a direct current of high frequency is applied. Treatment will last 40 minutes and be given 3 times a week for 4 weeks.
2. The control group will receive a mock transcutaneous electrical nerve stimulation (TENS) treatment with adhesive electrodes applied to the same points as in 1. The TENS machine will be adjusted at the output jack so no current flows but it will still retain visual signs of function.
Standard physiotherapy will be given to both groups, receiving treatment 5 times a week sometimes twice a day.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Motricity Index
2. Nottingham Health Profile
3. Standard Barthel Index

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/01/1997

Completion date
31/12/2001

Eligibility

Key inclusion criteria
Patients who have recently suffered a stroke.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
105 patients randomised (5 centres) (added 26/01/10; see publication

Key exclusion criteria
1. History of previous stroke
2. Computed Tomography (CT) scan showing haemorrhage
3. Stroke without limb weakness
4. Unable to co-operate with treatments
5. Initial coma
6. Pacemaker
7. Significant co-morbidity

Date of first enrolment
02/01/1997

Date of final enrolment

31/12/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Medicine
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
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United Kingdom
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+44 (0)20 7307 2622
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name

NHS Executive South East (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2008		Yes	No